

K962972

Oct. 11, 1996

**510(k) SUMMARY**

**I. ADMINISTRATIVE**

**Submitter:** Accunex Canada, Inc.  
202-2117 West 5th Avenue  
Vancouver, B.C.  
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**Contact Person:** Mr. Xianping Huang

**Date of Preparation:** July 30, 1996

**II. DEVICE NAME**

**Proprietary Name:** Surgicade™ Non-Sterile Gauze Sponges

**Common Name:** Wound Dressing

**Classification Name:** Gauze Sponge

**III. PREDICATE DEVICES**

Non-Sterile Gauze Sponges (Team Mfg., Inc.); K922055.  
Lorrex Cover Sponges, Non-Sterile (Lorrex Health Products); K942070

**IV. DEVICE DESCRIPTION**

Surgicade™ Non-Sterile Gauze Sponges are composed of USP Type VII gauze, available in thicknesses of 8 ply (2" x 2", 3" x 3", 4" x 4", 4" x 8"), 12 ply (2" x 2", 3" x 3", 4" x 4", 4" x 8"), and 16 ply (4" x 4").

**V. INTENDED USE**

Control bleeding, absorb body fluids, and protect wounds from contamination.

**VI. COMPARISON TO PREDICATE DEVICES**

Surgicade™ Non-Sterile Gauze Sponges are similar or identical in composition, function and intended use to legally marketed gauze sponges, such as Non-Sterile Gauze Sponges (Team Mfg., Inc.) and Lorrex Cover Sponges, Non-Sterile (Lorrex Health Products). All such devices are composed of absorbent gauze in various thicknesses and sizes, and have the same intended use.

Accordingly, Accunex Canada Inc. has concluded that the Surgicade™ Non-Sterile Gauze Sponges are safe and effective for their intended use and perform at least as well as legally marketed predicate devices, such as the Team Non-Sterile Gauze Sponges and Lorrex Non-Sterile Cover Sponges.